K012509

OCT - 9 2001

510 (k) Summary

pHoenix Electrolyte Calibration Set for the Dade/Behring Dimension® Chemistry Systems with MultiPLY™ Integrated Multisensor module installed

The products encompassed by this 510 (k) submission are Class II (75 JIX) In Vitro Diagnostic Solutions manufactured by pHoenix Diagnostics, Inc., 8 Tech Circle, Natick, MA 01760. The Calibration Set consists of an A, B and C level and is intended for use in calibrating Na^+, K^+, Cl^- and TCO_2 analytes on the Dade/Behring Dimension® Chemistry Systems. Dade/Behring Chemistry Systems, Inc. is the original equipment manufacturer (OEM) of the system.

The pHoenix products stated are currently cleared under docket K902675. Information herein will support pHoenix's position to extend the intended use of these products to the Dade/Behring Dimension® Chemistry Systems with MultiPLY™ Integrated Multisensor module installed. The MultiPLY™ Integrated Multisensor module measures Na^+, K^+, and Cl^- by using Integrated Multiple Technology means. The TCO_2 analyte is measured by the system's Ion Selective Electrode. The pHoenix Calibrator Reagents are intended to serve as direct replacements to like named products manufactured by Alko Diagnostic Corporation. pHoenix Product Calibrator A is equivalent to Alko Product A202-0. . pHoenix Product Calibrator B is equivalent to Alko Product A103-0. . pHoenix Product Calibrator C is equivalent to Alko Product A200-0.

pHoenix uses a similar composition, description and packaging design as that used by Alko Diagnostic Corporation in its products. pHoenix has shown performance equivalence of its products to Alko Diagnostic Corporation products in the following manner:

- Through a method comparison where results obtained on a Dade/Behring Dimension® Chemistry Systems with MultiPLY™ Integrated Multisensor module installed, calibrated with pHoenix products and compared with results obtained on the same analyzer calibrated with Alko products; and
- Through a precision study where pHoenix products were installed on a Dade/Behring Dimension® Chemistry Systems with MultiPLY™ Integrated Multisensor module installed and samples were measured over 20 runs.

pHoenix Diagnostics, Inc.

RAM NUNNA
PRESIDENT

8 TECH CIRCLE
NATICK, MA 01760

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 9 2001

Mr. Ram Nunna
President
pHoenix Diagnostic Inc.
8 Tech Circle
Natick, MA 01760

Re: k012509
Trade/Device Name: pHoenix Electrolyte Calibration Set for the Dade/Behring/Behring Dimension® Chemistry System
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: July 30, 2001
Received: August 6, 2001

Dear Mr. Nunna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 012509.

Device Name: pHoenix Electrolyte Calibration Set for the Dade/Behring/Behring Dimension® Chemistry System

Indications For Use:

Intended Use:

The pHoenix Electrolyte Calibrator Set is intended for use as calibrators to calibrate Na^+, K^+, Cl^- and TCO_2 for the Dade/Behring Dimension® Chemistry System with MultiPLY™ Integrated Multisensor module installed.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

Kevin Alexander Jr Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012509